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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/815,562

03/31/2004

Mohamed Zaiou

15670-076001 / 2002-119

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06/21/2006

BUCHANAN INGERSOLL LLP

(INCLUDING BURNS, DOANE, SWECKER & MATHIS)

P.O. BOX 1404

ALEXANDRIA, VA 22313-1404

EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/815,562

Applicant(s)

ZAIYOU ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-10 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-10 is/are allowed.
- 6) ☒ Claim(s) 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' response to office action dated February 3, 2006, filed on April 7, 2006 is acknowledged. Claims 3 and 10 have been amended. New claim 22 has been added. Claims 3-10 and 22 are currently under examination.

### ***Response to Amendments and Remarks***

#### ***Rejections Withdrawn***

35 U.S.C. § 112, Second Paragraph

The rejection of claims 3-10 under 35 U.S.C. 112, second paragraph is withdrawn in view of amendment to claim 3.

35 USC § 102

The rejection of claims 3-9 under 35 U.S.C. 102 is withdrawn in view of amendment to claim 3 and remarks at page 9 of the Amendment and Remarks.

35 USC § 103

The rejection of claim 10 under 35 U.S.C. 103 is withdrawn in view of remarks at page 10 of the Amendment and Remarks.

### ***New grounds of Rejection***

After carefully reviewing the amendments rejection of claims 3-10 have been withdrawn. However addition of new claim 22 has necessitated the following rejection. Though the attorney was informed informally by phone that all pending claims would be allowed provided the attorney authorizes for an Examiner's Amendment to claim 22, no agreement was reached. The amendment was suggested to delete the claim at the first instance, because amendment by replacing "consisting essentially of" with "consisting of" would have overcome the enablement rejection but would have raised an issue of duplication of claims. Please note that if claim 22 recites "consisting of" it will duplicate the amended claim 3. Thus deletion of claim 22 was suggested.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a peptide consisting of an amino acid sequence as set forth in SEQ ID NO: 2 from about amino acid 31-to 131; does not reasonably provide enablement for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with any peptide **consisting essentially of** an amino acid sequence as set forth in SEQ ID NO: 2 from about amino acid 31-to 131. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim.

Please note the new claim recites the phrase “consisting essentially of” which is interpreted as “comprising of” (see MPEP 2111.03, “Transitional phrases”).

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* 858 F.2d 731, 8 USPQ2d 1404 (Fed. Cir, 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, the amount of experimentation is required to practice the claimed invention is undue as the claims encompass an unspecified amount of polypeptides and variants/fragments of sequences set forth in SEQ ID NO: 2.

Note that claim 22 recites a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with a peptide consisting essentially of an amino

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acid sequence as set forth in SEQ ID NO: 2 from about amino acid 31-to 131. The recitation of the open language “consisting essentially of” (same as “comprising”) means the components not listed could be a part of the claimed peptide, for example there could be more than one sequence, and the sequence could have amino acid residues added to the N-terminal or C-terminal end of the sequence.

Further, the specification at page 16-18 indicates that the method according to the invention can be used to produce analogs, derivatives, conservative variations and cationic cathelin-like peptide variants. However, the claimed peptide once modified may not have the same properties of the parent peptide or retain the same function. Additionally there is no data provided demonstrative of a particular portion of the structure that must be conserved. Since the number of changes from the specific sequence are large, one of skill in the art would have to make and test each one to determine if it was a “cationic cathelin-like peptide and had the antimicrobial activity.

### ***Conclusion***

Claim 22 is rejected. Claims 3-10 have allowable subject matter

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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***Inquiries***

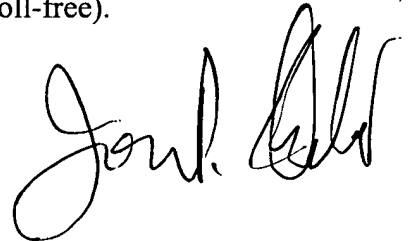
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

June 14, 2006



**Jon Weber**  
**Supervisory Patent Examiner**